510(K) SUMMARY

SUBMITTED BY:

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CONTACT NAME:

Monica Evelyn Giguere
Regulatory Affairs Specialist

DATE PREPARED:

December 13, 2004

DEVICE TRADE NAME:

BD Phoenix™ Automated Microbiology System – Cefotetan 2-64 µg/mL

DEVICE COMMON NAME:

Antimicrobial susceptibility test system-short incubation

DEVICE CLASSIFICATION:

Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645

PREDICATE DEVICES:

VITEK® System (PMA No. N50510) and BD Phoenix™ Automated Microbiology System with Gatifloxacin (K020321, May 23, 2002), Ofloxacin (K020323, April 14, 2002), and Levofloxacin (K020322, March 27, 2002).

INTENDED USE:

The BD Phoenix™ Automated Microbiology System is intended for the rapid identification and *in vitro* antimicrobial susceptibility testing of isolates from pure culture of most aerobic and facultative anaerobic gram-negative and gram-positive bacteria of human origin.

DEVICE DESCRIPTION:

The BD Phoenix Automated Microbiology System (Phoenix System) is an automated system for the rapid identification (ID) and antimicrobial susceptibility testing (AST) of clinically relevant bacterial isolates. The system includes the following components:

- BD Phoenix instrument and software.
- BD Phoenix panels containing biochemicals for organism ID testing and antimicrobial agents for AST determinations.
- BD Phoenix ID Broth used for performing ID tests and preparing AST Broth inoculum.
- BD Phoenix AST Broth used for performing AST tests only.
- BD Phoenix AST Indicator solution added to the AST Broth to aid in bacterial growth determination.

The Phoenix panel is a sealed and self-inoculating molded polystyrene tray with 136 micro-wells containing dried reagents. Organisms for susceptibility testing must be a pure culture and preliminarily identified as a gram-negative or gram-positive isolate. For each isolate, an inoculation equivalent to a 0.5 McFarland standard is prepared in Phoenix ID Broth.

The Phoenix AST method is a broth based microdilution test. The Phoenix System utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent. Measurements of changes to the indicator as well as bacterial turbidity are used in the determination of bacterial growth. Each AST panel configuration contains several antimicrobial agents with a wide range of two-fold doubling dilution concentrations.

The instrument houses the panels where they are continuously incubated at a nominal temperature of 35°C. The instrument takes readings of the panels every 20 minutes. The readings are interpreted to give an identification of the isolate, minimum inhibitory concentration (MIC) values and category interpretations, S, I, or R (sensitive, intermediate, or resistant).

DEVICE COMPARISON:

The BD Phoenix™ Automated Microbiology System demonstrated substantially equivalent performance when compared with the NCCLS reference broth microdilution method. This premarket notification provides data supporting the use of the BD Phoenix™ Automated Microbiology System gram-negative ID/AST or AST only Phoenix panels with this antimicrobial agent.

SUMMARY OF SUBSTANTIAL EQUIVALENCE TESTING:

The BD Phoenix™ Automated Microbiology System has demonstrated substantially equivalent performance when compared to the NCCLS reference broth microdilution method (AST panels prepared according to NCCLS M7). The system has been evaluated as defined in the FDA Draft guidance document, "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices", March 8, 2000.

Site Reproducibility

Intra- and inter-site reproducibility of this antimicrobial agent in the BD Phoenix System was evaluated at three sites using a panel of gram-negative isolates. Each site tested the isolates in triplicate on three different days using one lot of gram-negative Phoenix panels containing this antimicrobial agent and associated reagents.

The results of the study demonstrate for the this antimicrobial agent there was an overall intra-site reproducibility of greater than 90% and an overall inter-site reproducibility greater than 95% for the gram-negative isolates tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 15 2005

Ms. Monica Evelyn Giguere
Regulatory Affairs Specialist
BD Diagnostics Systems
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7 Loveton Circle
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Re: k043458
Trade/Device Name: BD Phoenix™ Automated Microbiology System
Cefotetan (2-64 µg/mL) - Gram-Negative ID/AST or AST
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices
Regulatory Class: Class II
Product Code: LON
Dated: March 8, 2005
Received: March 9, 2005

Dear Ms. Giguere:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

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510(k) Number: K043458

Device Name: BD Phoenix™ Automated Microbiology System for use with the antimicrobial agent cefotetan (2-64 µg/mL) - Gram-Negative ID/AST or AST only Phoenix panels.

Indications for Use:

The BD Phoenix™ Automated Microbiology System is intended for *in vitro* quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most gram-negative aerobic and facultative anaerobic bacteria isolates from pure culture for *Enterobacteriaceae* and Non-*Enterobacteriaceae* and most gram-positive bacteria isolates from pure culture belonging to the genera *Staphylococcus* and *Enterococcus*.

This premarket notification is for the addition of the antimicrobial agent cefotetan at concentrations of 2-64 µg/mL to gram-negative ID/AST or AST only Phoenix panels. Cefotetan has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the FDA-approved package insert for this antimicrobial agent.

Active *In Vitro* and in Clinical Infections Against:

Escherichia coli
Klebsiella species (including *K. pneumoniae*)
Proteus mirabilis
Proteus vulgaris
Providencia rettgeri
Serratia marcescens

Active *In Vitro* Against:

Citrobacter species (including *C. koseri* (*diversus*) and *C. freundii*)
Klebsiella oxytoca
Serratia species
Yersinia enterocolitica

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety